

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-150003	Application No. 10/010,283
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant Carl-Axel Bauer et al.	
		Filing Date November 13, 2001	Group Art Unit 1617

(37 CFR §1.98(b))

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
/JK/	A1	Ankerst <i>et al.</i> , "Tolerability of a high dose of budesonide/formoterol in a single inhaler in patients with asthma," <i>Pulm Pharmacol Ther.</i> , 16:147-51, 2003.
	A2	Arvidsson <i>et al.</i> , "Inhaled formoterol during one year in asthma: a comparison with salbutamol," <i>Eur Respir J</i> , 4:1168-1173, 1991.
	A3	Aubier <i>et al.</i> , "Salmeterol/Fluticasone propionate (50/500 µg) in combination in a Diskus® inhaler (Seretide®) is effective and safe in the treatment of steroid-dependent asthma," <i>Respir. Med.</i> 93:876-884, 1999.
	A4	Bartow <i>et al.</i> , "Formoterol: An Update of its Pharmacological Properties and Therapeutic Efficacy in the Management of Asthma," <i>Drugs</i> , 55(2):303-322, 1998.
	A5	Bond, "A strategy that works," <i>New Zealand Medical Journal</i> , p. 369, 28 August 1991.
	A6	"The British Guidelines on Asthma Management 1995 Review and Position Statement," <i>Thorax</i> , 52(Suppl 1):S1-21, 1997.
	A7	Collins <i>et al.</i> , "The Use of Corticosteroids in the Treatment of Acute Asthma," <i>Quarterly Journal of Medicine</i> , New Series, XLIV:259-73, 1975.
	A8	Corren <i>et al.</i> , "Twelve-Week, Randomized, Placebo-Controlled, Multicenter Study of the Efficacy and Tolerability of Budesonide and Formoterol in One Metered-Dose Inhaler Compared with Budesonide Alone and Formoterol Alone in Adolescents and Adults with Asthma," <i>Clinical Therapeutics</i> , 29(5):823-843, 2007.
	A9	Costain <i>et al.</i> , "Guidelines for management of asthma in adults: I—chronic persistent asthma," <i>BMJ</i> , 301:651-653, 1990.
	A10	Devidayal <i>et al.</i> , "Efficacy of nebulized budesonide compared to oral prednisolone in acute bronchial asthma," <i>Acta Paediatr</i> , 88:835-840, 1999.
	A11	Ebden <i>et al.</i> , "Comparison of two high dose corticosteroid aerosol treatments, beclomethasone dipropionate (500 µg/day) and budesonide (1600 µg/day), for chronic asthma," <i>Thorax</i> , 41:869-874, 1986.
	A12	Ellul-Micallef and Johansson, "Acute Dose-Response Studies in Bronchial Asthma with a New Corticosteroid, Budesonide," <i>Br. J. Clin. Pharmac.</i> , 15:419-422, 1983.
	A13	Ellul-Micallef <i>et al.</i> , "Budesonide: A New Corticosteroid in Bronchial Asthma," <i>Eur J Respir Dis.</i> , 61:167-173, 1980.
	A14	Engel <i>et al.</i> , "Single-dose inhaled budesonide in subjects with chronic asthma," <i>Allergy</i> , 46:547-553, 1991.
	A15	Fanta <i>et al.</i> , "Glucocorticoids in Acute Asthma," <i>American Journal of Medicine</i> , 74:845-851, 1983.
	A16	"FDA recommends easier-to-take asthma drug" <i>Florida Today</i> , Associate Press, November 24, 1999.
	A17	"Foradil: Fast relief that lasts," Ciba-Geigy Limited, Switzerland, Medical and Pharmaceutical Information, 1993
	A18	Hekking <i>et al.</i> , "Efficacy and tolerability of inhaled formoterol compared with inhaled salbutamol over three months", Symposium held during the 8th congress of the European Society of Pneumology, Freiberg, Germany, September 1989.
/JK/	A19	Hett <i>et al.</i> , "Large-Scale Synthesis of Enanti- and Diastereomerically Pure (R,R)-Formoterol," <i>Org. Process Res. Dev.</i> , 2:96-99, 1998.

Examiner Signature /Jennifer Kim/	Date Considered 03/02/2009
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/JK/	A20	Jackson <i>et al.</i> , "Benefit-Risk Assessment of Long-Acting $\beta_2$ -Agonists in Asthma," Drug Safety, 27(4):243-270, 2004.
	A21	Kesten <i>et al.</i> , "A Three-Month Comparison of Twice Daily Inhaled Formoterol Versus Four Times Daily Inhaled Albuterol in the Management of Stable Asthma," Am Rev Respir Dis, 144:622-625, 1991.
	A22	Kumar <i>et al.</i> , "Transient Effect of Inhaled Fluticasone on Airway Mucosal Blood Flow in Subjects with and without Asthma," Am J Respir Crit Care Med, 161:918-921, 2000.
	A23	Lampa <i>et al.</i> , "Antitracheobronchospastic Interaction <i>In Vitro</i> and <i>In Vivo</i> between Salbutamol and Flunisolide," Drugs Exptl. Clin. Res., XI(9):653-658, 1985.
	A24	Li, "Key Points of the new asthma guidelines," The Journal of Respiratory Diseases, 18:823-838, 1997.
	A25	McDonald <i>et al.</i> , "Evaluation of the combination inhaler of salbutamol and beclomethasone dipropionate in the management of asthma," Curr. Med. Res. Opin., 11(2), 1988.
	A26	McFadden, "Inhaled Glucocorticoids and Acute Asthma: Therapeutic Breakthrough or Nonspecific Effect?," Am J Respir Crit Care Med, 157:677-678, 1998.
	A27	Monthly Index of Medical Specialties (MIMS), Asthma, COPD, September 2007.
	A28	Monthly Index of Medical Specialties (MIMS), Bronchodilators and anti-inflammatories, December 1991.
	A29	Monthly Index of Medical Specialties (MIMS), Respiratory System, December, 1991.
	A30	Moore <i>et al.</i> , "Long-acting Inhaled $\beta_2$ -Agonists in Asthma Therapy," Chest, 113:1095-1108, 1998.
	A31	Nana <i>et al.</i> , "High-Dose Inhaled Budesonide May Substitute for Oral Therapy After an Acute Asthma Attack," Journal of Asthma, 35:647-655, 1998.
	A32	National Asthma Education and Prevention Program, "Guidelines for the Diagnosis and Management of Asthma," Expert Panel Report 2 July 1997 No. 97-4051.
	A33	Nyholm <i>et al.</i> , "Therapeutic advantages of twice-daily over four-times daily inhalation budesonide in the treatment of chronic asthma," Eur J Respir Dis, 65:339-345, 1984.
	A34	The Patents Act 1953 Exhibit "CRWB1." 1998
	A35	The Patents Act 1953 Exhibit "CRWB3." 1998
	A36	The Patents Act 1953 Exhibit "CRWB4." 1998
	A37	The Patents Act 1953 Exhibit "CRWB5." 1998
	A38	The Patents Act 1953 Exhibit "CRWB6." 1998
	A39	Poitiek <i>et al.</i> , "Comparison of formoterol, salbutamol and salmeterol in methacholine-induced severe bronchoconstriction" $\beta_2$ -Agonists In Methacholine-Induced Bronchoconstriction", Eur Respir J., 13:988-992, 1999.
	A40	Rabe <i>et al.</i> , "Effect of budesonide in combination with formoterol for reliever therapy in asthma exacerbations: a randomized controlled, double-blind study," Lancet, 368:744-753, 2006.
/JK/	A41	Rabe <i>et al.</i> , "Budesonide/Formoterol in a Single Inhaler for Maintenance and Relief in Mild-to-Moderate Asthma," Chest, 129:246-256, 2006.

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/JK/	A42	Rees, "β <sub>2</sub> Agonists and asthma," <i>BMJ</i> , 302:1166-1167, 1991.
	A43	Rosenborg <i>et al.</i> , "Relative systemic dose potency and tolerability of inhaled formoterol and salbutamol in healthy subjects and asthmatics," <i>Eur J. Clin Pharmacol.</i> , 56:363-370, 2000.
	A44	Rodrigo <i>et al.</i> , "Inhaled Flunisolide for Acute Severe Asthma," <i>Am J Respir Crit Care Med</i> , 157:698-703, 1998.
	A45	Rodrigo <i>et al.</i> , "Acute Asthma in Adults: A Review," <i>Chest</i> , 125:1081-1102, 2004.
	A46	Ryrfeldt <i>et al.</i> , "Pulmonary disposition of the potent glucocorticoid budesonide evaluated in an isolated perfused rat lung model," <i>Biochem Pharmacol.</i> , 38:17-22, 1989.
	A47	Schuh <i>et al.</i> , "A Comparison of Inhaled Fluticasone and Oral Prednisone For Children with Severe Acute Asthma," <i>New England Journal of Medicine</i> , 343:689-694, 2000.
	A48	Sears <i>et al.</i> , "Regular inhaled beta-agonist treatment in bronchial asthma," <i>Lancet</i> , 336:1391-1396, 1990.
	A49	Shepherd <i>et al.</i> , "Regular Versus Symptomatic Aerosol Bronchodilator Treatment of Asthma," <i>Br. J. Dis. Chest</i> , Vol. 75, pages 215-217 (1981).
	A50	Sue <i>et al.</i> , "A Comparison of Intravenous Hydrocortisone, Methylprednisolone, And Dexamethasone in Acute Bronchial Asthma," <i>Annals of Allergy</i> , 56:406-409, 1986.
	A51	Sykes <i>et al.</i> , "A study of the duration of the bronchodilator effect of 12 ug and 24 ug of inhaled formoterol and 200 ug inhaled salbutamol in asthma," <i>Respir. Med.</i> , 84:135-138, 1990.
	A52	Tan <i>et al.</i> , "Systemic Corticosteroid Rapidly Reverses Bronchodilator Subsensitization induced by Formoterol in Asthmatic Patient," <i>Am. J. Respiratory and Critical Care Medicine</i> , 156:28-35, 1997.
	A53	Tattersfield <i>et al.</i> on behalf of the Facet International Study Group, "Exacerbations of Asthma," <i>Am J Respir Crit Care Med</i> , 160:594-599, 1999.
	A54	The Dialog Corporation, "Formoterol launched in Switzerland", Accession No: S002557609000, 10/31/1990.
	A55	The Merck Manual of Diagnosis and Therapy, 16 <sup>th</sup> edition, 1992, page 653.
	A56	Treschel, "Foradil in medical practice: 7 case studies," Ciba-Geigy Limited, Switzerland (1992).
	A57	Treschel, AM Conference Report, A new long-acting beta-stimulator <b>1991</b>
	A58	U.S. Department of Health and Human Services, "Practical Guide for the Diagnosis and Management of Asthma," October 1997 NIH Publication No. 97-4053.
	A59	Vanzieleghem <i>et al.</i> , "A comparison of budesonide and beclomethasone dipropionate nasal aerosols in ragweed-induced rhinitis," <i>J. Allergy Clin. Immunology</i> , 79:887-892, 1987.
↓	A60	Waalkens <i>et al.</i> , "Budesonide and terbutaline or terbutaline alone in children with mild asthma: effects on bronchial hyperresponsiveness and diurnal variation in peak flow," <i>Thorax</i> , 46:499-503, 1991.
/JK/	A61	Wallin <i>et al.</i> , "Formoterol, a new long acting beta <sub>2</sub> agonist for inhalation twice daily, compared with salbutamol in the treatment of asthma," <i>Thorax</i> , 45:259-261, 1990.

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